Cullinan Oncology to Present Updated Data Demonstrating the Therapeutic Potential of CLN-081 in Patients with EGFR Exon 20 Insertion Mutation Positive Non-Small Cell Lung Cancer at the 2022 ASCO Annual Meeting

May 31, 2022

Updated data from Phase 1/2a study show median duration of response greater than 21 months and median progression-free survival of 12 months at 100 mg BID dose

Confirmed overall response rate of 41% at 100 mg BID dose

Continued favorable safety and tolerability profile observed in heavily pre-treated patients

CAMBRIDGE, Mass., May 31, 2022 (GLOBE NEWSWIRE) -- Cullinan Oncology, Inc. (Nasdaq: CGEM), a biopharmaceutical company focused on developing a diversified pipeline of targeted therapies for patients with cancer, today announced positive updated clinical research highlighting the therapeutic potential of CLN-081 in patients with epidermal growth factor receptor (EGFR) exon 20 insertion mutation positive non-small cell lung cancer (NSCLC). Findings will be presented on Friday, June 3 at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting as an oral presentation during the "Lung Cancer – Non-Small Cell Metastatic" session from 4:12- 4:24 p.m. CT (Abstract #9007). CLN-081 is being evaluated in an ongoing Phase 1/2a clinical trial in patients with NSCLC whose tumors harbor EGFR exon 20 insertion mutations that have progressed on or after prior therapy.

Summary of Key Clinical Results from Phase 1/2a Study of CLN-081 in NSCLC Patients with EGFR Exon 20 Insertion Mutations:

- As of May 2022, 73 patients have been treated across doses ranging from 30 to 150 mg twice daily (BID). Of the patients enrolled, 66% of patients had received two or more prior lines of treatment; 36% of patients had prior EGFR tyrosine kinase inhibitor (TKI) treatment, 55% of patients had received prior immunotherapy.
    - Among the 73 patients treated across all dose levels, 28 (38%) had confirmed partial response, 42 (58%) had stable disease and 3 (4%) had progressive disease according to RECIST guidelines (version 1.1).

- Of the 39 patients in the 100 mg BID dose group:
    - 16 (41%) had a confirmed partial response.
    - The estimated median duration of response (DOR) was greater than 21 months.
    - Median progression-free survival (PFS) was 12 months.

- The safety profile of CLN-081 was amenable for long-term treatment. The most common treatment-related adverse events in greater than 10% of patients were rash (80%), paronychia (32%), diarrhea (30%), fatigue (21%), anemia (19%), dry skin (18%), and nausea (16%), the majority of which were Grade 1/2. No Grade ≥3 rash or diarrhea occurred at doses <150 mg BID and discontinuations were uncommon.

"These data demonstrate a high response rate, improved response durability over standard of care treatment, and favorable safety and tolerability, supporting the rationale for CLN-081 in patients with NSCLC whose tumors harbor EGFR exon 20 insertion mutations," said Helena Yu, MD, Memorial Sloan Kettering. "These data demonstrate the potential for improvement upon the standard of care with effective and less toxic novel therapies to treat NSCLC harboring EGFR exon 20 insertion mutations where patients tend to have poorer outcomes than those with more common EGFR mutations."

"We believe CLN-081 has the potential to be a best-in-class treatment option for patients with NSCLC whose tumors harbor EGFR exon 20 insertion mutations with persisting unmet need. With an established high response rate and favorable safety and tolerability profile, we are encouraged to now see an updated durability of response profile that continues to improve," said Jeffrey Jones, MD, MPH, MBA, Chief Medical Officer, Cullinan Oncology. "We look forward to expeditiously advancing CLN-081 together with our collaborators at Taiho Pharmaceutical."

Cullinan Oncology will also present data on CLN-619 (Anti-MICA/MICB Antibody) in a poster presentation during the Developmental Therapeutics – Immunotherapy Poster Session (Abstract #TPS2688). The poster, "A Phase 1 Dose-Escalation Study to Investigate the Safety, Efficacy, Pharmacokinetics, and Pharmacodynamic Activity of CLN-619 (Anti-MICA/MICB Antibody) Alone and in Combination with Pembrolizumab in Patients with Advanced Solid Tumors," will be available on June 5 between 8:00 AM CDT-11:00 AM CDT.

Virtual and Live Investor Event

Cullinan Oncology will host an Investor Event on Saturday, June 4, 2022, at 7:00 a.m. CT, during which Dr. Helena Yu will present an overview of CLN-081 data shared at the 2022 ASCO Annual Meeting. Investors are invited to register to attend in-person or virtually through https://investors.cullinanoncology.com/news-events/events. A replay of the event will be available shortly after the conclusion of the event.

About CLN-081

CLN-081/ TAS6417 is an orally available small molecule being developed in collaboration with Taiho Pharmaceutical Co., Ltd. CLN-081 is designed as a next generation, irreversible EGFR inhibitor for the treatment of a genetically defined subset of patients with non-small cell lung cancer (NSCLC). CLN-081 is being investigated in a Phase 1/2a dose escalation and expansion trial evaluating oral, twice-daily, or BID, administration of various doses in patients with NSCLC harboring EGFRex20ins mutations, who have had at least one prior treatment with platinum-based chemotherapy or another approved standard therapy. CLN-081 has received Breakthrough Therapy Designation from the FDA.

About Cullinan Oncology

Cullinan Oncology, Inc. (NASDAQ: CGEM) is a biopharmaceutical company dedicated to creating new standards of care for patients with cancer. We innovate without borders to find the most promising clinic-ready cancer therapies, whether from our own discovery efforts or through exceptional engagement with our academic and industry partners. Anchored in a deep understanding of immuno-oncology and translational cancer medicine, we leverage our scientific excellence in small molecules and biologics to create differentiated ideas, identify unique targets, and select the optimal modality to develop transformative therapeutics across cancer indications. Powered by our novel research model, we push conventional boundaries from candidate selection to cancer therapeutic, applying rigorous early experimentation to fast-track only the most promising assets to the clinic and ultimately commercialization. As a result, our diversified pipeline is strategically built with assets that activate the immune system or inhibit key oncogenic drivers across a wide range of modalities, each with the potential to be the best or first in their class.

Our people possess deep scientific expertise, seek innovation openly, and exercise creativity and urgency to deliver on our promise to bring new therapeutic solutions to patients with cancer. Learn more about our Company at www.cullinanoncology.com, and follow us on LinkedIn and Twitter.

Forward-Looking Statements

This press release contains forward-looking statements of Cullinan Oncology, Inc. (Cullinan, we or our) within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, express or implied statements regarding Cullinan's beliefs and expectations regarding our preclinical and clinical development plans, clinical trial designs, clinical and therapeutic potential, and strategy of CLN-081, including but not limited to our expectations and beliefs around its safety and efficacy and plans for future CLN-081 studies. Any forward-looking statements in this press release are based on management's current expectations and beliefs of future events and are subject to known and unknown risks and uncertainties that may cause our actual results, performance or achievements to be materially different from any expressed or implied by the forward-looking statements. These risks include, but are not limited to, the following: uncertainty regarding the timing and results of regulatory submissions; success of our clinical trials and preclinical studies; risks related to our ability to protect and maintain our intellectual property position; risks related to manufacturing, supply, and distribution of our product candidates; risks related to the impact of COVID-19 affecting countries or regions in which we have operations or do business, including potential negative impacts on our employees, customers, supply chain and production as well as global economies and financial markets; the risk that any one or more of our product candidates, including those that are co-developed, will not be successfully developed and commercialized; the risk that the results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies; and success of any collaboration, partnership, license or similar agreements. These and other important risks and uncertainties discussed in our filings with the Securities and Exchange Commission, or SEC, including under the caption "Risk Factors" in our most recent Annual Report on Form 10-K and subsequent filings with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Moreover, except as required by law, neither Cullinan nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements included in this press release. Any forward-looking statement included in this press release speaks only as of the date on which it was made. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

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